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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 03/23/2004

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,544

Applicant(s)

HAMILTON ET AL.

Examiner

Joseph F Weiss Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 31-44 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 and 31-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 35-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2 & 3.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. This application contains claims 22-24, 31-34 drawn to an invention nonelected without traverse and claims 41-44 non-elected with traverse in Paper No.6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-21, 36-40 & 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 2-21, 36-40 & 42-44 recites the limitation "the invention" in the first line. There is insufficient antecedent basis for this limitation in the claim.

In regards to claims 1-21, applicant sets forth in line 8, applicant sets forth the structural element "a pressure representative of the appliance" but such cannot be structure, please rephrase.

Also in regards to claims 1-21, applicant expressly sets forth a demand valve having as part of its sub-structure a valve assembly responsive to chamber pressure, but such being a multitude of valves itself. Such would not be viewed by one of ordinary skill in the art to be what a demand valve comprises, but instead such being a valve

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assembly having several valves, one of which is the demand valve. (see the enclosed demand valve references as evidence of such).

In regards to claim 4, the claim is indefinite because it further defines the valve controller as comprising a second valve, yet by dint of the logic of claim construction analysis this would mean that the main valve controller already was claimed as comprising a first valve, yet no first valve has yet been set forth as being a sub-structure of the main valve controller. I.e. logic dictates that the "the main/first valve/assembly be set forth and then the sub structure of the valve)

5. Claim 7 recites the limitation "the nebulizer outlet" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the third valve" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the third valve" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the nebulizer outlet" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "said at least one adjustable pressure regulator" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

In light of the valve definiteness issue to the base claims, art is applied to the extent possible and to which the claims can be understood. One significant step the examiner suggests to resolve the definiteness is that applicant appears to be claiming a demand valve

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assembly that consists of many sub-component/sub-assembly valves or valve sets, applicant should consider claiming the invention in this manner to optimize clarity.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 6, 8-10, 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatch (US 4838257).

In regards to claim 1, Hatch discloses In a continuous positive airway pressure apparatus for supplying breathable gas from a pressurized source to an individual's breathing appliance, which appliance has an inlet for receiving the gas and an inhalation/exhalation valve for routing the gas to the individual's lungs and the exhaled air to the atmosphere, the apparatus comprising: a demand valve (12) having a supply inlet port adapted to be connected to the pressurized source (10), an outlet port adapted to be connected to the appliance's inlet (14), a reference chamber (25) and a valve assembly (11/12/15/16) responsive to the reference chamber pressure with a pressure representative of the appliance inlet pressure for connecting and disconnecting the inlet port to and from the outlet port (note role of monitor 20); and at least one back pressure regulator connected to the pressurized source (20) and the reference chamber for setting the pressure in the reference chamber at a selected level above atmospheric

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pressure. (note the interconnectivity of 10, 20, 54, 16 via the electronics & computer 17).

In regards to claim 2, Hatch discloses the demand valve includes an outlet chamber upstream from the outlet port, the pressure in the outlet chamber being representative of the pressure in the breathing appliance inlet. (See fig 3, sub-structure of 12 between diaphragm 42 & 14)

In regards to claim 3, Hatch discloses the valve assembly includes a first or main valve connected between the inlet and outlet ports (42, 44, 46) and a main valve controller responsive to the difference in the pressure in the reference chamber and the representative appliance inlet pressure for causing the first valve to open and connect the inlet port to the outlet port when the representative appliance inlet pressure falls below the pressure in the reference chamber and for causing the main valve to close to disconnect the inlet from the outlet port when the representative of the breathing appliance inlet pressure rises to the pressure in the reference chamber. (note controller 17 & the disclosure regarding how it takes pilot valve & pressure monitor feedback to modulate the valving).

In regards to claim 4, Hatch discloses the main valve controller comprises a second valve. (note valve 11, which as a provider of the data feedback loop, provides data to 17 for controlling the valves).

In regards to claim 6, Hatch discloses the main valve comprises a diaphragm (42) valve with first and second actuating chambers disposed on opposite sides of the diaphragm (25 & 48), the area of the diaphragm exposed to the second chamber being

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smaller than the area of the diaphragm exposed to the first chamber whereby the main valve will remain closed when the pressure in the two actuating chambers is substantially the same and will open when the pressure in the first chamber falls below the pressure in the second chamber by a preset amount. (note that only circumferential bulge of diaphragm 42 is exposed to 48).

In regards to claim 8, Hatch discloses the second valve comprises a diaphragm valve with the reference chamber and a second chamber disposed on opposite sides of a pressure sensing diaphragm, the second chamber being in fluid communication with the outlet port. (note fluid connectivity of 11 via airway appliance)

In regards to claim 9, Hatch discloses both chambers of the main diaphragm valve are connected to the inlet port, the connection to the first chamber including a restrictor for restricting the flow rate. (note element 44)

In regards to claim 10, Hatch discloses the second diaphragm valve further includes a normally closed pilot valve connected to the first chamber of the main valve, the pilot valve opening to connect the first chamber of the main valve to the second chamber of the second valve in response to the movement of the sensing diaphragm as a result of the pressure in the second chamber of the second valve falling below the pressure in the reference chamber. (note pilot valves 15 & 16).

In regards to claim 21, The invention of claim 2 further including a nozzle disposed upstream of the outlet port and in an educting relationship with the outlet chamber so that the pressure in the outlet chamber varies with the flow rate of gas

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through the nozzle to compensate for pressure losses between the outlet port and the breathing appliance inlet.

IN regards to claims 35-37, Hatch discloses such as set forth in the rejection to claims 1-3 which is herein incorporated by reference.

Claim Rejections - 35 USC § 103

8. Claims 11, 14, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatch.

In regards to claim 11, Hatch discloses the pilot valve including a biased member which maintains the pilot valve normally closed (linear actuator 31), but does not expressly disclose use of a spring as the linear actuator, a commonly known mechanical equivalent to the electro-mechanical linear actuator of Hatch.

It is noted that applicant's specification does not set forth the use of a spring, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 14, Hatch substantially disclose the claimed invention to include user input in terms of manipulating a selector and manual adjustability correlated to the patient's respiratory cycle, but does not disclose said at least one pressure regulator comprise two pressure regulators, i.e. a duplication of a known part for a known purpose.

It is noted that applicant's specification does not set forth this routine duplication of a known part for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 19, Hatch substantially disclose the claimed invention except for the other pressure regulator is not manually adjustable by an operator in the field and functions to set the pressure in the reference chamber at a set pressure above the exhalation reference pressure during the inhalation phase, but it has all the structure of applicant's claimed invention and hence would be fully capable of performing the functions as set forth by applicant. (i.e. no lockout structure is being claimed, just a capability of the previously set forth structure).

It is noted that applicant's specification does not set forth this capability, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

9. Claims 5,7, 12 & 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatch as applied to claims 4, 6, 9 & 38 above, and further in view of Davenport.

In regards to claim 5, Hatch substantially discloses the instant application's claimed invention, but does not explicitly disclose a pressurized nebulizer outlet and a third valve responsive to the status of the second valve for connecting and disconnecting the nebulizer outlet to the inlet port when the second valve is closed and opened, respectively. However, Davenport disclose such (310 of Fig 9 & supporting text). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Davenport and used them with the device of Hatch. The suggestion/motivation for doing so would have been to provide nebulized medicament simultaneously with ventilatory support to ameliorate the pulmonary disease process that has required ventilation support. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 7, Hatch substantially discloses the instant application's invention to include the third valve is a diaphragm valve with first and second chambers disposed on opposite sides of the diaphragm, the first chamber being in fluid communication with the first chamber of the main valve, but does not explicitly disclose the second chamber of the third valve being in fluid communication with the nebulizer

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outlet and with the second chamber of the main valve through a flow restrictor.

However, Davenport disclose such (310 of Fig 9 & supporting text). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Davenport and used them with the device of Hatch. The suggestion/motivation for doing so would have been to provide nebulized medicament simultaneously with ventilatory support to ameliorate the pulmonary disease process that has required ventilation support. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 12, Hatch substantially discloses the instant application's claimed invention including the third valve is a diaphragm valve having first and second actuating chambers disposed on opposite sides of the diaphragm, the first chamber being in fluid communication with the first chamber of the main valve, but does not explicitly disclose the second chamber being in fluid communication with the pressurized nebulizer outlet. However, Davenport disclose such (310 of Fig 9 & supporting text). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made,

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it would have been obvious to one of ordinary skill in the art to have taken the features of Davenport and used them with the device of Hatch. The suggestion/motivation for doing so would have been to provide nebulized medicament simultaneously with ventilatory support to ameliorate the pulmonary disease process that has required ventilation support. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 38, Hatch & Davenport discloses such as set forth in the rejection to claim 5 which is herein incorporated by reference.

10. Claims 13, 15-17, 20 & 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatch as applied to claims 3, 14, 19 37 above, and further in view of Foote.

In regards to claim 13, Hatch substantially discloses the instant application's claimed invention to include said at least one adjustable pressure regulator includes a line with a flow restrictor connected between the pressurized source and the reference chamber (note the venturi) but does not explicitly disclose a first adjustable poppet valve connected between said line upstream from the flow restrictor and atmosphere. However, Foote disclose such (see fig 3, poppets 73 & 76 & supporting text). The references are analogous since they are from the same field of endeavor, the

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respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Foote and used them with the device of Hatch. The suggestion/motivation for doing so would have been to equalize pressure during operation of the device. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 15, Hatch substantially discloses the instant application's claimed invention to include the reference chamber connected to the pressurized source through a restrictor and but does not explicitly disclose each pressure regulator includes a poppet valve, each poppet valve having an inlet and an outlet, the outlets being in fluid communication with the atmosphere, the inlet of one of the poppet valves being in constant fluid communication with the reference chamber upstream from the restrictor, and further including a fourth valve for placing the inlet of the other poppet valve in fluid communication with the reference chamber, upstream of the restrictor, in response to the closure of the main valve. However, Foote disclose such (see fig 3, poppets 73 & 76 & supporting text). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Foote and used them with the device of Hatch. The

suggestion/motivation for doing so would have been to equalize pressure during operation of the device. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 16, suggested device substantially disclose the claimed invention except for the except for both pressure regulators are manually adjustable, a commonly known manner of making a regulator adjustable.

It is noted that applicant's specification does not set forth manual adjustability, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 17, suggested device substantially disclose the claimed invention except for wherein the fourth valve is a diaphragm valve, an old and well known feature in the demand valve arts.

It is noted that applicant's specification does not set forth use of this old and well known feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

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Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 20, Hatch substantially discloses the instant application's claimed invention but does not explicitly disclose each of the pressure regulators includes a poppet valve and the selector comprises a diaphragm valve. However, Foote disclose such (see fig 3, poppets 73 & 76 & supporting text & selector diaphragm 90). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Foote and used them with the device of Hatch. The suggestion/motivation for doing so would have been to equalize pressure during operation of the device. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 39, Hatch & Foote discloses such as set forth in the rejection to claim 13, which is herein incorporated by reference.

In regards to claim 40, Hatch & Foote substantially disclose the claimed invention to include user input in terms of manipulating a selector and manual adjustability correlated to the patient's respiratory cycle, but does not disclose said at least one

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pressure regulator comprise two pressure regulators, i.e. a duplication of a known part for a known purpose.

It is noted that applicant's specification does not set forth this routine duplication of a known part for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

11. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hatch & Foote as applied to claim 17 above, and further in view of Davenport.

In regards to claim 18, the suggested device substantially discloses the instant application's claimed invention to include fourth valve includes first and second chambers disposed on opposite sides of the diaphragm with the second chamber being in fluid communication with the reference chamber but does not explicitly disclose the first chamber being in fluid communication with the nebulizer outlet. However, Davenport disclose such. The references are analogous since they are from the same (field of endeavor or problem solving area). At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Davenport and used them with the suggested device. The suggestion/motivation for doing so would have been to provide nebulized medicament simultaneously with ventilatory support to ameliorate the pulmonary disease process

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that has required ventilation support. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

12. Applicant's arguments filed 12 Aug 03 have been fully considered but they are not persuasive.

Base claim 41 has several limitations that the other base claims do not possess and base claim 41 omits several limitations that the other base claims do possess, being that the scopes are not consonant, the restriction is deemed proper, applicant's arguments are not persuasive and it is made final as noted above.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6571796, 6318366, 6237594, 6116242, 5666945, 5360000, 5237987, 5074298, 5040529, 4971050, 4877023, 4278110, 4141356, 3952773, 3834383, 2608971, 2608200

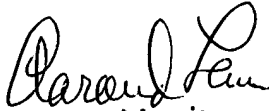
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JFWeiss
2/27/04


Aaron J. Lewis
Primary Examiner